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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/389,082 09/02/99 FITZGERALD

S 104161

EXAMINER

IM52/0523

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CROSS, L

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/389,082

Applicant(s)

FITZGERALD ET AL.

Examiner

LaToya I. Cross

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1743

5/23/01

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- OK
4. Claim 3 contains the phrase "substantially fills the area". What do Applicants' intend "substantially fill" to mean?

- OK
5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the

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claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "comprises three storage wells", and the claim also recites "preferably arranged in a line" which is the narrower statement of the range/limitation.

OK Claim 14 appears to be a duplicate of claim 2, as both claims are dependent upon claim 1 and recite the same limitations.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6, and 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,843,767 to Beattie (hereinafter Beattie '767).

Applicants' claimed invention is directed to an assay assembly comprising a chip on which an array of reactive species is immobilized, and storage well having a base and side walls, wherein the storage well contains the chip.

Beattie '767 teaches a microfabricated porous apparatus for detecting of binding reactions. The apparatus of Beattie '767 comprises a substrate containing individual regions/sites arrayed across the substrate for binding reactions to take place, and biomolecules of predetermined structure which are fixed into each of the individual

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regions/sites. In Beattie '767 the substrate containing individual regions/sites is a nanoporous glass wafer. Each of the regions/sites is a tapered conical well (storage well) bonded to a face of the glass wafer (col. 5, lines 27-48, lines 53-57). Filled polymers, epoxy resins and related composites are materials used in the arrays. The biomolecules of predetermined structure are disclosed as being binding reagents which are immobilized onto the walls of the wells. The binding reagents are effective for carrying out binding reactions such as those involving small molecules, macromolecules, particles and cellular systems (col. 10, example 2; col. 29, line 66 - col. 30, line 43). See figures 1A and 1B.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated within the meaning of 35 USC 102, in view of the teachings of Beattie '767.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie '767 ~~as anticipated by Beattie '767~~ in view of Great Britain publication 2,147,698 to Albon et al (hereinafter Albon et al '698).

The disclosure of Beattie '767 pertinent to the claimed invention is described in

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the previous section.

Beattie '767 fails to disclose the use of hot or cold formed projections for retaining the chips in the storage wells. Also, Beattie '767 does not disclose a plurality of carrying trays arranged in a stack.

The use of projections in storage wells for holding assaying items in place is conventional as shown by Albon et al '698. Albon et al '698 teach a test apparatus for immunoassay comprising a holder having a plurality of inserts for reaction wells and a tray having a plurality of reaction wells. The inserts contain specific immunological sensitization. The inserts are removably mountable in the holder via "stud-and-socket" press fitting or screw mounting or by adhesive bonding.

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to use such projections as disclosed by Albon et al '698 to removably mount the insert insides of the reaction wells.

With respect to the carrying trays being arranged in a stack, this is an obvious manner of carrying several trays which would allow the trays to be packaged easily and also allow easier shipping.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Beattie '767 and Albon et al '698.

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Citation of Relevant Prior Art


10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC 
May 20, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700